

Appl. No. 09/877,999 Amdt. dated Dec. 11, 2003 Reply to Office action of Sept. 15, 2003

REMARKS/ARGUMENTS

Claims 1-4, 6-9, and 11-19 remain in this application.

Claims 5 and 10 have been canceled.

Claims 15-18 have been withdrawn as the result of an earlier restriction requirement. Applicant retains the right to present claims 15-18 in a divisional application. The Examiner is authorized to cancel said claims without prejudice to the subject matter thereof upon an indication that this application is in allowable condition.

In response to the Office Action of Sept. 15, 2003, Applicant requests re-examination and reconsideration of this application for patent pursuant to 35 U.S.C. 132.

Claims 1-4, 6-9, 11-14, and 19 are under consideration in this Office Action.

Rejections under 35 USC 112

Claims 1-4, 6-9, 11-14, and 19 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to

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particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4, 6-9, 11-14 and 19 are deemed by the Examiner to be indefinite because it is unclear if the compositions may combine "non-ionic hydrophobic units" only with the "mixtures of ionizable and charged units", or if "non-ionic hydrophobic units" may also be combined with just ionizable or just charged units. Similarly, in part "c." of the claims it is unclear if the compositions may combine "non-ionic hydrophobic units" only with the "mixtures of ionizable and charged units", or if "non-ionic hydrophobic units" may also be combined with just ionizable or just charged units.

Claim 19 is also deemed to be indefinite because it requires that a hydrophobic unit must be synthesized from a hydrophobic compound selected from vinyl monomers, vinyl oligomers, or vinyl polymers, and that the hydrophobic compound must be either vinylterminated poly(lactide) or vinyl terminated poly(epsilon caprolactone). However, the Examiner points out that neither vinyl terminated poly(lactide) nor vinyl terminated poly(epsilon caprolactone) is synthesized from vinyl monomers, vinyl oligomers, or vinyl polymers, because these compounds have only one vinyl group, at the terminus. Part "a." of claim 19 was indicated to be too indefinite to allow a meaningful search.

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Accordingly, claims 1 and 19 have been amended to:

a) clarify that the diblock, multiblock and random copolymers include *either ionizable units, charged units or mixtures of ionizable and charged units originating from a first monomer, in combination with non-ionic hydrophobic units originating from a second monomer;*

additionally, claim 19 has been further amended to clarify that *said ionizable or charged block includes hydrophobic repeating units which are biodegradable polyesters selected from the group consisting of poly(lactide) and poly( $\epsilon$ -caprolactone).*

Basis for these amendments may be found *inter alia* at pages 22-24 of the specification.

Accordingly, it is respectfully submitted that the above amendments clarify the claims, without raising new issues or including new matter, and it is urged that said amendments be entered and the rejections under 35 USC 112 be withdrawn.

**Rejections under 35 USC 102(b)**

Claims 1-4 and 14 stand rejected under 35 U.S.C. 102(b) as being anticipated by Yokoyama et al (US Patent 5,510,103, issued 4/23/96).

Yokoyama has been analyzed by the Examiner as teaching micelles composed of diblock copolymers comprising hydrophilic

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blocks and blocks comprising ionizable residues and hydrophobic repeating units. In one embodiment of the invention the Examiner indicates that the hydrophilic block is non-ionizable polyoxyethylene, and the ionic block ionizable moiety is an acetic or propionic acid group (see claim 1, especially line 27 wherein R3 may be propionic acid). Propionic acid comprises a hydrophobic segment (ethylene group) that is deemed to serve as a non-ionic hydrophobic repeating unit. The propionic acid group is indicated as capable of being converted between charged and uncharged states by altering the pH of the medium, or by chemical modification, e.g. covalent addition of an uncharged group (see claim 1, lines 30-35. Claim 14 is included in this rejection because it is a product by process in which the claimed product is disclosed in the cited art, rendering the process by which it was made irrelevant.

The claims have now been amended to clarify that ***the ionizable units, charged units or mixtures of ionizable and charged units originate from a first monomer, and that the non-ionic hydrophobic units originate from a second monomer.***

The reference to Yokoyama utilizes forms a block copolymer represented by Formula I or II which derives from a poly (ethylene oxide) segment linked to a homopolymer. The propionic acid segment bears both a hydrophobic segment and an ionizable

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group and therefore distinguishes from the invention as instantly claimed. It is respectfully submitted that this clarification of the claim to overcome Yokoyama further reiterates Applicants' previous position, and should not be deemed to be a new issue requiring further consideration and/or search. Thus, it is respectfully requested that this ground of rejection be withdrawn.

Rejections under 35 USC 102(e)

Claims 1-9 and 11 stand rejected under 35 U.S.C. 102(e) as being anticipated by Allwohn et al (US Patent 6,372,203, issued 4/16/02). Allwohn is analyzed by the Examiner as teaching micellar compositions comprising diblock copolymers of hydrophilic saccharide polymers and polymers of charged monomers comprising hydrophobic repeating units. See column 4, lines 56-59; column 5, lines 24-67; column 6, line 43 to column 7, line 8; and column 10, lines 39-46. In one embodiment the Examiner indicated that the charge can be viewed as permanent, i.e. a quaternary amine (see column 5, lines 34-37. In another embodiment, the Examiner indicates that the charge is subject to pH (secondary and tertiary amines, see column 5, lines 34-37). The hydrophobic repeating units required by the claims can be considered to be the vinyl groups, acrylate derivatives, C<sub>1</sub> to C<sub>12</sub> alkyl groups, or aryl groups (see column 5, lines 37-55). In

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one embodiment the copolymer comprising the charged and hydrophobic entities is a polymer of vinyl esters (see column 6, line 64 to column 7, line 8).

While Allwohn teaches compositions whose consistency may be built up by micelle formation with the aid of suitable emulsifiers, fatty acids, fatty alcohols, etc. Allwohn fails to teach or suggest formulations which can form supramolecular self assemblies as required by the instant invention. The formation of supramolecular self-assemblies implies hydrophobic interaction and the inclusion of the hydrophobic domains drives the self-assembly. Allwohn fails to teach or suggest these features, this it is respectfully requested that this ground of rejection be withdrawn.

Furthermore, the claims, as presently amended, preclude the addition presence of the required cosmetic carrier of Allwohn, by virtue of the "consisting essentially of" language.

Thus, it is respectfully submitted that the claims now read over the Allwohn reference, and it is requested that this rejection be withdrawn.

Claims 1-4, 12, 13, and 19 stand rejected under 35 U.S.C. 102(e) as being anticipated by Kabanov et al (US Patent 6,440,743, issued 8/27/02). Kabanov is analyzed by the Examiner

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as teaching micellar compositions comprising diblock, multiblock, and random graft copolymers comprising a hydrophilic, nonionic polymer and a polycationic polymer with hydrophobic repeating units. See entire document, especially the abstract, column 3, line 30 to column 6, line 64; and column 10, lines 4-49. In one embodiment the charge can be viewed as permanent, i.e. a quaternary amine (see column 10, lines 11 and 12. In another embodiment, the charge is subject to pH (secondary and tertiary amines, see column 10, lines 9 and 10). The hydrophobic repeating units required by the claims can be considered to be the ethylene, propylene, butylene, pentylene, or hexylene (see column 10, lines 6-9). The hydrophilic block may comprise acrylamide or acrylamide derivatives.

Kabanov teaches a method for delivering a polynucleotide to a cell comprising administering to the cell an effective amount of a composition comprising a noncovalent complex of said polynucleotide and a polymer comprising a plurality of covalently bound segments.

The claims, as instantly presented, are drawn to supramolecular self-assemblies of a polyelectrolyte, not a method for delivering a polynucleotide to a cell which requires the formation of a noncovalent complex of said polynucleotide and a polymer comprising a plurality of covalently bound

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segments. The use of a polynucleotide in the formation of the supramolecular self-assembly is precluded by Applicants' use of the phrase "consisting essentially of" in the preamble of the claim, as instantly presented. Thus, it is respectfully submitted that the instant claims differentiate over Kabanov et al and it is requested that the rejection thereof be withdrawn.

#### SUMMARY

In light of the foregoing remarks and amendment to the claims, it is respectfully submitted that the Examiner will now find the claims of the application allowable. Favorable reconsideration of the application is courteously requested.

Respectfully submitted,

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